## REMARKS

This Amendment is being filed within the three month statutory period for response scheduled to end on November 15, 2002, and accordingly, no fee is believed to be due

Claims 7-20 are currently pending in this case. By this amendment, claims 7-9 have been amended, claims 1-6 have been canceled, and new claims 10-20 have been added.

## Claim Objections

The Examiner has objected to claim 8 under 37 C.F.R. § 1.126 for improper numbering. Applicants have re-listed the elements of claim 8 as a-f instead of g-l, as requested by the Examiner. As such, applicants believe the Examiner's objections to the claims have been fully overcome.

## Drawings

The Examiner has objected to Figures 4a-5c under 37 C.F.R. § 1.83(a). Applicants enclose herewith for the Examiner's approval a full set of proposed formal drawings, including Figs. 4a-5c which replace the hand sketches of these drawings that were originally submitted. These drawings better illustrate details of the structures described in the specification.

The Examiner has further objected to the drawings under 37 C.F.R. § 1.84(p)(5) as not including reference numerals 16d and 32a that were referred to in the specification. Applicants have amended the specification at page 13, line 16 to properly refer to reference numeral 16a instead of 16d. With regard to reference numeral 32a, applicants submit that reference numeral 32a does appear in the originally filed drawings, in particular, on Figures 7a-7d.

In view of the foregoing, applicants believe that the Examiner's objections to the drawings have been overcome.

## Rejections Under 35 U.S.C. § 112

The Examiner has rejected claims 1, 3 and 5 under 35 U.S.C. § 112, first paragraph. In particular, the Examiner has indicated that the term "needle-like," which appears in each of claims 1, 3 and 5 is indefinite, and similarly that the term "suture-like" that appears in claim 3 is indefinite. The Examiner has also rejected claim 1, indicating that the term "adjusting means" is ambiguous because it covers more than one type of adjusting means referred to in the specification. Applicants respectfully disagree that the fact that term "adjusting means" covers more than one embodiment is a proper grounds for rejection under § 112. "Breadth of a claim is not to be equated with indefiniteness" and "if the scope of the subject matter embraced by the claim is clear . . . then the claims comply with 35 U.S.C. 112, second paragraph." MPEP, Section 2173.04.

Nevertheless, applicants have canceled original claims 1, 3 and 5, and no newly added claims recite any of the terms cited above. Accordingly, the Examiner's rejections are now moot.

## Rejections Under 35 U.S.C. § 102

Claims 1, 3, 6 and 7 stand rejected under 35 U.S.C. § 102(e) in view of U.S. Patent No. 5,899,909 to Claren et al. ("Claren"). As a preliminary point, the applicants respectfully disagree with the Examiner's characterization of the Claren reference to the extent that it has been stated to disclose an adjusting means for adjusting the tape after implantation, wherein the adjusting means includes a suture-like element that passes through the tape. Claren discloses a tape that can be comprised of a woven mesh, but none of the "threads" that make up the woven fabric independently constitute a means for adjusting the tape as suggested by the Examiner. There is simply no support in the Claren reference for adjustment of the disclosed device by any means other than pulling on the ends of the tape at the time of implantation. Figure 17 of Claren, specifically referred to by the Examiner, similarly provides no support for this position. Figure 17 illustrates a tape having a

visible color mark 38 at the longitudinal center of the tape to assist the surgeon in properly placing the tape relative to the urethra. See Col. 5, lines 17-20. No independent adjustment means is indicated, suggested or inherent in Figure 17.

With reference now to particular claims, amended independent claims 7 and 9, and newly added independent claims 10 and 15 each recite as an element an "*expandable chamber*" associated with the tape. Claren neither teaches nor suggests such a feature, and accordingly, does not anticipate these claims. With regard to new independent claims 14 and 16, both claims require a filamentary element *having a first end affixed to the tape and a second end* wherein *manipulation of the second end increases or decreases the tension of the tape to thereby increase or decrease support to the urethra respectively*. As indicated above, the only adjustment mechanism disclosed or suggested by Claren is via manipulation of the ends of the tape itself. There is no independent "filamentary element" disclosed by Claren that can be manipulated independent of the tape ends to adjust the tape after implantation. Accordingly, Claren does not anticipate independent claims 14 or 16, or any of claims 17-20 which depend from claim 16. Reconsideration is respectfully requested.

Rejections Under 35 U.S.C. § 103

The Examiner has further rejected claims 1,2, 4, 5 and 8-9 under 35 U.S.C. § 103(a) as being unpatentable over Claren in view of U.S. Patent No. 6,117,067 to Gil-Vernet ("Gil-Vernet"). Applicants respectfully traverse the Examiner's rejection.

Gil-Vernet does disclose an approach to adjusting a urethral support device using an expandable container. The disclosed device includes a sling portion positioned beneath the urethra, an expandable container located **remotely** from the sling and **embedded within the abdominal region**, with the two being connected by individual sutures or the like (3, 4) so that, via the sutures (i.e., indirectly), expansion of the expandable container provides additional support to the urethra.

As discussed in the specification of the present application at page 3, first paragraph, the device disclosed by Gil-Vernet has several drawbacks. First and foremost, it is a relatively complex device that requires a much more invasive

procedure than would otherwise be necessary to implant the urethral support device itself. For the Gil-Vernet device to work as described, it is imperative that the lower base 10 of the expandable chamber 1 be positioned "in the appropriate anatomical region in order to obtain sufficient support for its lower face." Col. 5, lines 54-57. In other words, the expandable chamber must rest on a sufficiently firm surface to enable upward expansion of the chamber to translate into tension on the sutures that will lift the supported organ. In the illustrated embodiment, the expansion chamber is sufficiently embedded within the abdominal region so that it rests on muscular mass 2 (see Fig. 1). Given its required placement, a second separate mechanism that rests closer to the skin (see control cell or capsule 8 and connecting tube 7) must be provided to enable fluid injection into the expansion chamber. As stated in the specification at Col. 4, lines 58-67,

> . . . the present invention provides for the said chamber to communicate, by means of a fine tube of biocompatible synthetic material, with a small capsule which will be coupled in a subcutaneous arrangement, but sufficiently close to the skin of the patient so that from the outside a puncture can be made with a fine hypodermic needle in order to gain access to the said control cell or capsule for the purpose of introducing or extracting liquid in the required manner to adjust the desired fixing height of the anatomical organ.

Thus, implantation of the Gil-Vernet device not only requires separate implantation of the expansion chamber within the abdomen on a suitable supporting structure, but also requires implantation and positioning of the separate mechanism required to enable filling or emptying of the expansion chamber. Finally, even following a successful implantation, the location of the expansion chamber is less than optimal given the fact that abdominal pressure (i.e. from coughing or laughing) will regularly expose the expansion chamber to stress and distortion.

The combination of Gil-Vernet and Claren does not alleviate the above-described problems, but rather compounds them. The device disclosed by Claren is a tape that forms a loop around the urethra, with the tape extending the entire length between the abdominal fascia and under the urethra. Because it is a tape (rather than the sutures disclosed by Gil-Vernet), a significant amount of ingrowth will occur along the length of the tape. Thus, an expansion chamber such as that disclosed by

Gil-Vernet that is positioned remotely from the urethra simply will not work because the tissue ingrowth would be too significant to allow the tape to move upwards sufficiently to transfer the increased support to the urethra.

The invention as presently described and claimed is a novel approach that overcomes the problems described above. One embodiment of the present invention provides a simple mechanism for adjusting a urethral sling that 1) is incorporated into the sling itself so that implantation is essentially no more complicated or invasive than implantation of the sling itself; 2) is positioned so that expansion of the expansion chamber *directly* provides increased support to the urethra; and 3) is positioned so that the expansion chamber is directly accessible for fluid injection without the need for additional injection mechanisms.

Referring now to the claims of the present application, independent claim 10 recites a substantially flat tape and

> an expandable chamber affixed to the tape so that, when the tape is implanted, the expandable chamber is positioned substantially below the urethra, wherein the expandable chamber is expandable by injection of a fluid therein, and wherein such expansion directly provides increased support under the urethra.

Amended independent claims 7 and 9, and new independent claim 15 recite these elements in a similar fashion. Gil-Vernet and Claren, either alone or in combination, fail to disclose or suggest such an expandable chamber that is positioned substantially below the urethra and that, when expanded, directly provides additional support to the urethra. As indicated above, a urethral support device incorporating these features is novel and advantageous in that it results in a simple design that can be implanted in a simple, minimally invasive manner.

To the extent that the Examiner's rejection is based on the premise that it would have been obvious to one skilled in the art to both combine the Gil-Vernet and Claren references, and to further substantially modify the Gil-Vernet adjustment mechanism itself and its location relative to a urethral sling device to achieve the device described and claimed by applicants, applicants respectfully submit that such a position is based on impermissible hindsight in view of the present invention itself. Accordingly, applicants respectfully submit that each of independent claims 7, 9 10

and 15 are patentable in view of the Gil-Vernet and Claren references. Reconsideration is requested.

The Examiner has also rejected claim 8 under § 103 over the Gil-Vernet and Claren references. Claim 8 now recites implanting a tape to form a sling around the urethra, and following implantation, "**post-surgically** injecting a **bulking agent between the tape and the urethra**." Neither Gil-Vernet nor Claren, alone or in combination, teach or suggest the use of a bulking agent, let alone post-surgically injecting such a bulking agent between the tape and urethra to provide a means for post-surgically adjusting urethral support. Accordingly, claim 8 is patentable over the cited references as well, and reconsideration is requested.

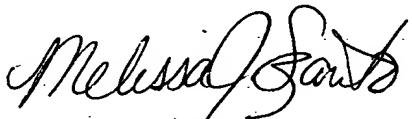
## CONCLUSION

In view of the above amendments and arguments, applicants believe that each of pending claims 7-20 are patentable over the cited art and in condition for allowance. Reconsideration and allowance is respectfully requested.

As this amendment is being filed within the three month statutory period for response that is scheduled to end on November 15, 2002. The Commissioner is hereby authorized to charge any fees that may be required, to deposit Account No. 10-0750/GYN-045/MJS. This Authorization is being submitted in triplicate.

Should any minor points remain prior to issuance of a Notice of Allowance, the Examiner is requested to telephone the undersigned at the below-listed telephone number.

Respectfully submitted,



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## VERSION WITH MARKINGS TO SHOW CHANGES MADE

In the Specification:

The first paragraph appearing on Page 13, lines 15-24 has been amended as follows:

Figs. 3f-g illustrate an alternate embodiment of affixing tape 12 to the distal end 17a of needle 10. A detachable blunt tip [16d] 16a having a connecting post 15, attaches to the distal end 17a by means of a mounting hole 15a to accept post 15. Post 15 may be securely attached to hole 15a either by compression fit, mating threads or other convenient attachment methods. Distal end 17a further defines a groove 23 of varying depth to allow the end of tape 12 connected to post 15 to transition from within hole 15a to the exterior of needle 10. Along with the embodiment of Figs. 3a-e, this embodiment allows the surgeon to affix tape 12 to needle 10 just prior to the surgical procedure. One advantage is the ability to use a tape 12 constructed of, at least in part, a natural material 13.

In the Claims:

Claims 1-6 have been canceled.

7. (Amended) A method for treating female urinary incontinence comprising the steps of:

g) providing a curved needle-like element defining in part a curved shaft;

h) attaching a first end of a tape to the needle, the tape having an expandable chamber for receiving fluid therein;

i) passing the needle and tape into the body;

j) attaching a second end of the tape to the needle and passing the needle and tape into the body to form a sling around the urethra, whereby the expandable chamber is positioned substantially below the urethra;

k) leaving the tape implanted in the body; and

l) adjusting the tape after implantation by injecting fluid into or removing fluid from the expandable chamber to thereby directly increase or decrease support under the urethra.

8. (Amended) A method for treating female urinary incontinence comprising the steps of:

[g)] a) providing a curved needle-like element defining in part a curved shaft;

[h)] b) attaching a first end of a tape to the needle;

[i)] c) passing the needle and tape into the body;

[j)] d) attaching a second end of the tape to the needle and passing the needle and tape into the body to form a sling around the urethra;

[k)] e) leaving the tape implanted in the body; and

[l)] f) post-surgically injecting a bulking agent between the tape and urethra.

9. (Amended) A device for supporting an internal anatomical structure comprising a mesh tape and an expandable chamber having the ability to contain a variable amount of a [bulking agent] fluid, wherein the expandable chamber is affixed to the mesh tape and positioned between the mesh tape and anatomical structure so that expansion of the expandable chamber directly provides increased support under the anatomical structure.

The following new claims have been added:

10. (New) A surgical device for treating female urinary stress incontinence comprising:

a) a substantially flat tape for implanting into the lower abdomen of a female to provide support to the urethra; and

b) an expandable chamber affixed to the tape so that, when the tape is implanted, the expandable chamber is positioned substantially below the urethra, wherein the expandable chamber is expandable by injection of an injectable agent therein, and wherein such expansion directly provides increased support under the urethra.

11. (New) The surgical device according to claim 10, wherein the injectable agent is a bulking agent.

12. (New) The surgical device according to claim 10, wherein the injectable agent is a fluid.

13. (New) The surgical device according to claim 10, wherein the expandable chamber is comprised of a hydrogel.

14. (New) A surgical instrument for treating female urinary stress incontinence comprising:

a) a substantially flat, flexible tape for implanting into the lower abdomen of a female patient to provide support to the urethra, and having a length and a width; and

b) a filamentary element extending along at least a portion of the length of the tape and having a first end affixed to the tape and a second end, the suture element passing through the tape at least once, whereby manipulation of the second end increases or decreases tension on the tape, thereby providing increased or decreased support to the urethra respectively.

15. (New) A method for treating female urinary incontinence comprising the steps of:

e) providing a substantially flat tape for implanting into the lower abdomen of a female patient to provide support to the urethra;

f) providing an expandable chamber for accepting a fluid therein affixed to the tape;

g) implanting the tape and expandable chamber within the female to form a sling around the urethra, so that the expandable chamber is positioned substantially below the urethra;

h) post-operatively adjusting the sling by injecting fluid into or removing fluid from the expandable chamber to thereby directly increase or decrease respectively support under the urethra.

16. (New) A method for treating female urinary incontinence comprising the steps of:

a) providing a substantially flat, flexible tape for implanting into the lower abdomen of a female patient to provide support to the urethra, the tape having a length, and having a filamentary element extending along at least a portion of the length, the filamentary element having a first end affixed to the tape and a second end and passing through the tape at least once; and

b) manipulating of the second end of the filamentary element to increases or decreases tension on the tape to thereby increase or decrease respectively support to the urethra.

17. (New) The method according to claim 16, wherein the filamentary element is a suture.

18. (New) The method according to claim 16, wherein the filamentary element is positioned substantially along a center of the tape.

19. (New) The method according to claim 16, wherein the second end of the filamentary element is accessible via the patient's vagina.

20. (New) The method according to claim 16, wherein the filamentary element is woven into through the tape at a plurality of locations.